NDA 21-174/S-003, S-004

Wyeth Ayerst Laboratories
P.O. BOX 8299
Philadelphia, PA 19101-8299

Attention: Timothy K. Ressler
Worldwide Regulatory Affairs, Global Brand Management

Dear Mr. Ressler:

Please refer to your supplemental new drug applications dated March 2 and April 11, 2001, received March 5 and April 12, 2001 respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mylotarg (gemtuzumab ozogamycin) for Injection.

These "Changes Being Effected" supplemental new drug applications provide for revisions to your Mylotarg US package insert. We note that S-004 supersedes S-003.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted April 11, 2001. Accordingly, supplemental application S-004 is approved effective on the date of this letter. S-003 will be retained in our files.

Please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sean Bradley, R.Ph., Regulatory Project Managers, at 301-594-5750.

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research